

the formation of crust even in a deep skin injury, and promoted the formation of granulation tissue and epidermal tissue. The Examiner further states that when the topical preparation was applied to a hardly curable bedsore in human patients, reduction of injured area and remedy of wound was observed. The Examiner admits that Konishi et al. do not specifically teach treating keloid or hypertrophic scar formation.

The Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time of the invention to have employed topical application of acetylsalicylic acid in the treatment of open wound skin injuries as taught by Konishi et al., and also employed such compositions to treat potential keloids and hypertrophic scars that may form as a result of such injuries. The Examiner asserts that one skilled in the art would expect a reasonable degree of success that compositions containing acetylsalicylic acid would also be effective in treating keloids and hypertrophic scars, based on the teachings of Capelli-Schellpfeffer.

The Position of Applicants

Applicants respectfully traverse the position of the Examiner.

An object of Konishi et al. is to provide a drug for the treatment of skin injuries, particularly hardly curable diseases, such as a bedsore. Specifically, Konishi et al. disclose that acetylsalicylic acid is effect for treating skin injuries, particularly an open wound such as a bedsore.

However, as the Examiner admits, Konishi et al. fail to teach or suggest **a treatment for keloid or hypertrophic scar formation**, as required by Applicants' claims. Specifically, it is not taught or suggested that in a course of therapy for wound or dermal injuries, keloid or hypertrophic scar formation is inhibited by locally administering acetylsalicylic acid. The Examiner relies upon the teachings of Capelli-Schellpfeffer (hereafter abbreviated as "C-S") to remedy the deficiencies of Konishi et al., stating that even though C-S teaches treatment on closed wounds, it is nonetheless employed to treat scars, and therefore one would expect similar results with an open wound.

Applicants respectfully assert that one of ordinary skill in the art would not have combined the teachings of Konishi et al. and C-S, as asserted by the Examiner, because the references refer to distinct stages of treatment. Furthermore, even if the references were

combined in the manner suggested by the Examiner, the invention of Applicants' claims would remain unobvious.

An object of the present invention is to inhibit keloid and/or hypertrophic scar formation, in a course of therapy of wound or dermal injury. Applicants' specification discusses the phrase "in a course of therapy of wound or dermal injury" as including open wound stage, **but not including closed wound stage or the stage after the formation of hypertrophic scar or keloid**. (Please see page 2, lines 6-7; page 3, lines 21-26; and Test 1 on pages 15-16 of Applicants' specification.)

Applicants' method is distinct from a method for treatment of an **already formed** keloid or hypertrophic scar, as in C-S. The term "wound" in C-S never refers to an open wound, as explained on page 6, lines 16-19 of C-S, which states, "The terms 'healed wound' or 'scar' include closed wound or a wound surface that is closed by regrowth of epithelial barrier. A wound is 'closed' after an open wound has been re-epithelialized. Closed wounds can result in the formation of a scar, ..."

Therefore, it is evident that Applicants' claimed methods are distinct from those of C-S, because the term "wound" in C-S never refers to an open wound. The Examiner acknowledges that C-S refers only to treatment of closed wounds, in the first line on page 7 of the Office Action.

As discussed above, Konishi et al. disclose a treatment on open wound stage, while C-S disclose treatment on the stage of healed wound, namely the stage **after** scar or keloid formation. Thus, the combination of Konishi et al. and C-S, as purported by the Examiner, is untenable as the methods refer to distinct stages of treatment.

Additionally, C-S does not disclose that acetylsalicylic acid is effective for treating hypertrophic scar or keloid which is already formed, or for inhibition of keloid and/or hypertrophic scar formation, with any working example. Specifically, acetylsalicylic acid was never **topically** administered to the patients in order to treat a scar or a keloid. In fact, C-S reveals that even when acetylsalicylic acid is orally administered to the patient suffering from post-operative scar, acetylsalicylic acid is **not effective** and therefore, **salicylic acid-treatment is further necessary**.

The Examiner's rejection is based upon the assertion that one of ordinary skill in the art would expect a reasonable degree of success that compositions containing acetylsalicylic acid would also be effective in treating keloids and hypertrophic scars, based upon the teachings of C-S. (Please see the last paragraph on page 6 of the Office Action.) However, this position is untenable, as there is no data in C-S supporting that topical acetylsalicylic acid is effective for treating keloid or hypertrophic scar. (Please see the detailed comments set forth on pages 10-12 of the Appeal Brief filed October 13, 2009.)

The Examiner's purported combination of Konishi et al. and C-S is untenable, as Konishi et al. disclose a treatment on open wound stage, while C-S disclose treatment on the stage of healed wound, namely the stage **after** scar or keloid formation. Furthermore, neither reference teaches or suggests the use of acetylsalicylic acid for inhibition of scar or keloid formation.

For the reasons set forth above, the invention of Applicant's claims 5-7 are unobvious over the cited combination of references. Withdrawal of the rejection is respectfully requested.

Conclusion

Therefore, in view of the foregoing remarks, it is submitted that the ground of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

If, after reviewing this Response, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

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